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PATENT APPLICATION

for

A TRANSVERSE SUSPENSION DEVICE

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A TRANSVERSE SUSPENSION DEVICE

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present invention relates to a transverse suspension device, in particular, but not exclusively, a transverse suspension screw for anterior cruciate ligament (ACL) fixation in the femoral tunnel.

[0002] Transverse securing devices are being increasingly used for secure fixation of ACL replacement grafts in the femoral tunnel during ACL reconstruction surgery. One such device known as the bone mulch ^{TM} screw is available from Arthrotek^{R}.

[0003] The bone mulch screw has a hollow body section with an opening at either end thereof. The tip of the screw is stepped having a sharp narrow leading section followed by a slightly wider trailing section. The trailing end of the tip is joined to the body section on one side of the said body section only, leaving a gap at the leading end of the body section so that bone mulch material can be forced therethrough and into the femoral tunnel after fixation. A suture passing loop must be located over the end of the partially inserted tip in the femoral tunnel and it is for this reason that the tip is stepped so that the leading end is as narrow as possible to maximise efficiency in the difficult step of locating a suture loop over the leading end of the bone mulch tip when it first protrudes into the femoral tunnel. Once the suture loop is in position, the bone mulch screw may be advanced further so that the stepped tip bores through the medial wall of the femoral tunnel until the thicker section of the tip fully extends transversely across the tunnel. The graft may then be pulled into the tunnel by passing it over the transverse pin after attaching it to one end of the looped suture and pulling the other end. Unfortunately, because the graft must be pulled over the pin at the blind end of the femoral tunnel it is necessary to ream out bone from inside the femoral tunnel so as to create sufficient space for the graft to be pulled over the pin without becoming caught between the end of the femoral tunnel and the pin. By reaming out bone from the end of the femoral tunnel, the compression of the graft against the tunnel wall is decreased lengthening the process of healing and fixation. Furthermore, the looping of the suture is not a straightforward step and requires an

arthroscopic view via the tibial tunnel and may also require several attempts before the loop is successfully located over the leading end of the tip.

[0004] Alternatives to such transverse suspension pins include interference cross pins which interfere against a bone block in bone-patella tendon-bone graft fixation. A suitable device for such procedures is the BiLok ™ screw. However, such techniques are not appropriate for pure tendon grafts such as the double-looped semitendinosus and gracilis (DLSTG) hamstring graft which is one of the strongest and stiffest grafts available and does not suffer from a number of complications associated with the bone-patella tendon-bone graft.

[0005] According to a first aspect of the present invention there is provided a transverse suspension device for ACL graft fixation in a femoral bone tunnel comprising a body section and a smooth head section forming the leading end of the device, the body and smooth head sections each being cannulated along the entire lengths thereof; the head section comprising a recess-engaging section extending proximally from the distal end thereof and operable to engage with a recess formed in the bone tunnel, and a graft loop support section between the recess-engaging section and the body section adapted to stably support the graft loop thereover.

[0006] By the term stably support, is meant that the portion of the graft loop located over the loop support section is prevented from movement along the longitudinal axis of a femoral or other bone tunnel in which the device is located transverse thereto.

[0007] Preferably, the body section has a wider cross-section than the graft loop support section to provide an abutment surface at the proximal end of the graft loop support section. Preferably, the abutment surface provides a graft abutment in use, to urge the graft loop into contact with the opposite wall of a bone tunnel.

[0008] Advantageously, in use, the said abutment surface urges the graft loop onto the opposite wall of the femoral tunnel and thus the bone and the graft loop are encouraged to graft to each other.

[0009] Therefore, according to a second aspect of the present invention there is provided a transverse suspension device for ACL graft fixation in a femoral bone tunnel comprising a body section and a smooth head section forming the leading end

of the device, the body and smooth head sections each being cannulated along the entire lengths thereof; the head section comprising a recess-engaging section extending proximally from the distal end thereof and operable to engage with a recess formed in the bone tunnel, and an abutment surface located between the body section and the recess-engaging section adapted to urge the graft against the opposite wall of the bone tunnel in use.

[0010] Preferably in relation to the second aspect of the present invention the transverse suspension device comprises a graft loop support section which is, preferably, adapted to stably support the graft loop thereover. Preferably, the graft loop support section is located between the recess-engaging section and the body section.

[0011] Preferably, the graft loop support section is of constant, preferably, circular, cross section. Typically, the head section is located on the same longitudinal axis as the body section.

[0012] Preferably, at least a part of the recess-engaging section tapers outwardly from the leading end thereof. Preferably, the recess-engaging section comprises a rounded nose section at the leading end thereof which, preferably, terminates the tapered section at the leading end of the device. Preferably, at least the major part of the recess-engaging section is frustoconical.

[0013] Preferably, the device is cannulated along the entire length thereof. Preferably, the head section extends distally from the distal end of the body section.

[0014] Preferably, the body section is suitably adapted for secure fixation, in use, in a tunnel transverse to the femoral tunnel, preferably, by interference with the tunnel wall. For instance, the body section may comprise a series of external protrusions such as ribs extending along the body section but tapering outwardly towards the trailing end to prevent the head of the device coming out of the femoral tunnel. Preferably, however, the body section is externally threaded so that the device may be conveniently screwed into position.

[0015] Preferably, the body section protrusions or threads provide a larger dimension for the body section between smaller dimension areas and, preferably, at least the larger dimension cross-section is wider than the dimension of the graft loop

support section, more preferably, the smaller dimension cross-section areas of the body section are also wider than the graft loop support section.

[0016] As mentioned above, preferably, at least a part of the smooth head tapers outwardly from the leading end thereof to form a tapered section of the head. The smooth head may also include a non-tapered section between the tapered section and the body section previously described as the graft loop support section. Preferably, the widest diameter of the smooth head is less than the outer diameter of the body section. Preferably, the body section itself is not tapered but has a substantially uniform overall diameter along the length thereof subject to thread undulations or protrusions on the exterior surface thereof. The cannulated interior of the device may be wider at its trailing end to accommodate a suitable fixation device to assist location of the device in position.

[0017] Advantageously, by having the body and head section, cannulated, the device may be advanced along a guide wire and located under the loop of a graft pre-positioned in the femoral tunnel. An additional advantage is provided by the tapered head section which increasingly compresses the graft as it advances thereunder during fixation. A threaded or ribbed body section may still further compress the graft forwards and outwards when the smooth head is short enough to completely advance beneath the first loop so that then the body section impinges on the graft directly. However, compression is chiefly effected by an abutment surface at the distal end of the body section. Preferably, the abutment surface is in the form of a flange, which is, preferably, annular. Graft compression advantageously contributes to graft incorporation by assisting tunnel wall bonding of the graft. The abutment surface may be a flange.

[0018] Therefore, according to a third aspect of the present invention there is provided a method of ACL graft ligament fixation comprising the steps of:-

[0019] forming a femoral tunnel for graft fixation therein;

[0020] forming a transverse tunnel for intersecting the femoral tunnel;

[0021] locating a graft loop in the femoral tunnel in such a manner that the open face of the loop faces the intersection of the transverse tunnel,

[0022] passing at least a part of the head section of a transverse suspension device according to the first or second aspect of the present invention through the graft loop via the transverse tunnel.

[0023] By passing the smooth head of the device through the graft loop, the graft is progressively compressed outwardly against the femoral tunnel walls before being stably located therein via the graft loop support section.

[0024] Preferably, after location of the graft loop in the femoral tunnel, a guide wire is advanced thereunder from the transverse tunnel using a suitable viewing device such as an arthroscope. The suspension device may then be passed along the guide wire.

[0025] Preferably, a dilation device is passed along the guide wire prior to the suspension device to dilate the loop in the graft after the guide wire is advanced thereunder, and, preferably, the dilation device is forced into the opposite wall of the femoral tunnel to create a recess therein.

[0026] The dilation device may then be removed and the suspension device may then be passed along the guide wire.

[0027] Preferably, the suspension device is advanced under the graft loop. Preferably, the recess-engaging section is advanced into the recess in the opposite wall of the femoral tunnel and, preferably, the body section is advanced into the femoral tunnel. Preferably, the abutment surface of the body section urges the graft loop onto the opposite wall of the femoral tunnel.

[0028] Advantageously, the insertion of the dilation device opens the graft loop allowing the suspension device to pass freely thereunder.

[0029] Advantageously, the smooth surface of the head section prevents damage to the graft during its fixation and the method of locating the head section under the loop avoids the need for complex suture loop passing and looping steps. Furthermore, because the head section compresses the graft loop directly against the walls of the femoral tunnel in a single step, damage to the graft is minimised.

[0030] Preferably, the head of the device is advanced as far as the opposite wall of the femoral tunnel. The head may also be advanced into the opposite tunnel wall a short distance to provide more secure fixation, if required.

[0031] However, as the cannulation extends through the head section the leading tip of the head section does not typically terminate in a sharp point but is typically rounded into a convex tip with a centrally disposed cannular hole.

[0032] Preferably, the diameter of the cannular hole at the tip of the device is in the range 0.1-3mm, more preferably 0.5-1.5mm, most preferably 0.8-1.2mmm.

[0033] Preferably, the diameter of the cannular hole at the trailing end of the device is between 0.1-15.0mm, more preferably 1-10mm, most preferably 2-8mm.

[0034] Preferably, the length of the head section is between 1-25mm, more preferably between 2-20mm, most preferably between 5-15mm.

[0035] Preferably, the length of the body section is between 5-50mm, more preferably between 10-40mm, most preferably between 20-30mm.

[0036] Preferably, the maximum width of the head section is between 1-15mm, more preferably between 2-8mm, most preferably, between 3-8mm. An especially preferred width is 5-7mm.

[0037] Preferably, the width of the body section excluding any protrusions is between 2-15mm, more preferably, between 3-12mm, most preferably 5-12mm.

[0038] Preferably, the minimum width of the graft loop support section of the head section, is between 0.5-10mm, more preferably, between 2-8mm, most preferably, between 2-5mm.

[0039] Preferably, the trailing end of the device is adapted to receive a suitable tool for use during fixation of the device. The tool is preferably suitable to locate the device in the transverse tunnel via a push fit or screw fit mechanism.

[0040] An embodiment of the invention will now be described by way of example only and with reference to the accompanying drawings in which:

[0041] Figure 1 is a perspective view of a transverse suspension device in accordance with the present invention;

[0042] Figure 2 is a trailing end view of the transverse suspension device of figure 1;

[0043] Figure 3 is a sectional view through the transverse suspension device of figure 1;

[0044] Figure 4 is a partial view of the right knee joint showing the femoral and tibial tunnels prepared for ACL reconstruction;

[0045] Figure 5 is a partial view of the right knee joint illustrating the use of an A-Tech guide;

[0046] Figure 6 is the view of figure 4 showing the drilling of the transverse tunnel;

[0047] Figure 7 is a view of figure 4 showing the guide wire and tap in position;

[0048] Figure 8 is a view of figure 4 showing the graft being pulled into position;

[0049] Figure 9 is a cross sectional view of a dilation device;

[0050] Figure 10 is a cross sectional view of the femoral tunnel prior to location of the suspension device;

[0051] Figure 11 is a cross sectional view of the femoral tunnel with the suspension device in place; and

[0052] Figure 12 is a view of figure 4 showing the transverse suspension device stably securing the graft loop in the femoral tunnel.

[0053] Referring to figures 1, 2 and 3, a transverse suspension device 2 has a tubular body section 4 and a co-axial head section 6 joined to and protruding from the leading end 8 of the body section 4. The transverse suspension device 2 is cannulated along the length of the axis thereof so that it may be passed along a guide wire in use. The body section 4 is externally screw threaded along its entire length and the head section 6 includes a trailing part 10 coaxial with the body section 4 but of a narrower outer diameter and a frustoconical nose section 12 extending from the leading end of the trailing part 10 and having the narrower end forming the leading end of the nose section. The tip of the nose section is rounded in a convex manner and includes the exit port 14 of the cannulated hole of the device at its centre.

[0054] The hollow interior of the device extends from the trailing end in the form of a central tubular recess which is stepped into a radially narrower keyhole section 20, midway along the length of the body section, which extends forwardly through the remainder of the body section as far as the leading end thereof. The keyhole section 20 includes three radially inwardly directed longitudinally extending vanes 22, 24 and 26. The vanes are equally circumferentially spaced apart around the interior wall of the tube but have their trailing ends slightly axially recessed with

respect to the beginning of the keyhole section. Each vane has a leading face which is arcuate in end section and a trailing face which is substantially flat in end section and extends radially away from the longitudinally extending apex of the vane back to the internal circumferential wall of the hollow keyhole section. Thus, each vane forms a radially inwardly directed ridge which ridge extends longitudinally along the length of the keyhole section and provides the means for a suitable co-engaging tool to engage therewith for screwing the device into position during surgery.

[0055] Referring to figure 4, a partial view of the right knee joint 30 includes a tibia section 32 and a femur section 34 articulating therewith in the usual manner. In the illustration shown, the posterior cruciate ligament 36 is shown extending between the tibia and the femur but the anterior cruciate ligament is missing. A tibial tunnel 38 of standard construction extends between the anterior surface of the tibia and the tibial plateau. A femoral tunnel 40 extends from the intercondylar notch towards the lateral femoral aspect and includes a passing pin tunnel 42 which extends from the proximal end 44 of the femoral tunnel to exit at the lateral femoral aspect of the femur 46. The method of preparation of the tibial and femoral tunnels are in accordance with standard techniques known in the art.

[0056] Referring to figure 5, a transverse femoral guide 48 of known construction includes a femoral locator 50 comprising an elongate straight rod 52 with a femoral locator head 54 located at the proximal end thereof and which is sized to fit within the femoral socket 40. The straight rod section 52 is designed to extend from an anchor section 56, through the tibial tunnel and intercondylar notch. An arcuate guide arm 58 of standard construction extends from the lateral side of the anchor 56 in an arcuate manner and includes an adjustable sleeve section 50 for multiple position fixation with respect thereto. The head 62 of the guide arm sleeve 60 accommodates a cannulated guide wire bullet 64 which extends therethrough. The positioning of the head of the sleeve 62 is such that it extends parallel with the femoral locator head 54 and the cannulated bullet extends through an appropriately sized perpendicular aperture in the head of the guide arm sleeve 62 so that it may be advanced towards the head of the femoral locator. In use, a small lateral incision is made on the surface of the knee joint to remove any soft tissue so that the cannulated bullet may be advanced until it firmly locates on the lateral epicondyle. The length of the transverse tunnel to

be drilled can be determined from the measurements on the transverse bullet according to known techniques. The 2.4mm guide wire may then be drilled through the femur until it touches the femoral locator. Thereafter, the guide 48 may be removed together with the femoral locator leaving the guide wire 66 in position. The guide wire 66 is then advanced to penetrate bone on the opposite wall of the femoral tunnel by approximately 1cm.

[0057] Referring to figure 6, the guide wire 66 is shown as it is being advanced towards the opposite wall of the femoral tunnel. Thereafter, it may be over drilled with an 8mm cannulated drill 68 to create the transverse tunnel 70 which intersects with the femoral tunnel 40. An arthroscope (not shown) may be inserted into the femoral tunnel via the intercondylar notch to assess penetration of the drill 68 into the femoral socket, as the drill should not penetrate the opposite wall of the femoral socket. At this point in the procedure, the 2.4mm guide wire pin 66 may be removed and replaced with a thinner 1mm guide wire of the transverse screw. Thereafter, the cannulated drill 68 may be removed.

[0058] Referring to figure 7, a cannulated tap 72 is shown being advanced along the transverse tunnel 70 so as to pre-thread the tunnel in preparation for receiving the transverse suspension device screw. After tapping of the transverse tunnel 70 is complete, the tap 72 may be removed leaving the guide wire in position. The guide wire is then retracted away from the medial wall of the femoral tunnel to provide a gap which is sufficient to allow insertion of the graft into the femoral tunnel.

[0059] Referring to figure 8, a graft loop 74 is shown located in position in the femoral tunnel 40. The graft includes sutures 76 threaded therethrough and tied at the proximal end to the end of a passing pin 78. In practice, the passing pin is advanced through the tibial tunnel, intracondylar notch and femoral tunnel and passed out through the passing pin tunnel 42 to appear at the lateral femoral aspect. The sutures may then be pulled to locate the loop of the graft in the correct position in the femoral tunnel. Care should be taken so that the face of the loop faces the intersection with the transverse tunnel 70. The screw guide wire extending down the transverse tunnel 70 may then be located under the loop using an arthoscope 80 via the same transverse tunnel 70. The arthoscope 80 and guide wire may be advanced together

under the loop and once successively located the arthoscope may be retracted and removed taking care to retain the guide wire in position.

[0060] Referring to figure 9, a dilation device 100 is shown having a tubular shaft 102, a handle section 104 and a nose section 108. The nose section 108 is frustoconical in shape, and has a rounded leading end 110. The frustoconical section extends distally from a shoulder section 106 at the trailing end thereof, the said shoulder section extending proximally with a constant cross-section as far as the shaft 102, co-axial therewith but of a slightly larger cross-section than the shoulder. The dilation device 100 is cannulated 112 along the entire length thereof so as to be passed along the guide wire such that it dilates the graft loop 74 as it passes transversely through the bone tunnel. The dilation device 100, is advanced along the guide wire with sufficient force to create a recess in the opposite wall of the femoral tunnel in which the frustoconical nose section 12 of the suspension device 2 may be accommodated. Accordingly, the dilation device is suitably dimensioned to be complimentary to the suspension device in this respect. The dilation device 100 is then retracted leaving the graft loop 74 sufficiently dilated such that the suspension device 2 can be advanced therethrough. When retracting the dilation device 100, care is taken to retain the guide wire in position.

[0061] Referring to figure 10, the cannulated screw is shown located over the guide wire and advancing towards the dilated graft loop 74

[0062] Referring to figure 11, the suspension device 2 is shown fully advanced into the femoral tunnel with its frustoconical nose section 12 embedded in the recess 13 formed in the opposite wall of the femoral tunnel. The body section 4 being of a wider diameter than the trailing part of the head section 6, provides an annular abutment for the graft loop residing on the trailing part 10 and as the suspension device advances the annular abutment urges the graft loop against the opposite wall of the bone tunnel thus encouraging the graft and the bone to graft to each other.

[0063] Thereafter, the guide wire may be removed. The final position of the cannulated transverse suspension device screw is shown in figure 12 with the outer wall of the head of the screw and the leading end of the body section urging the graft into contact with the walls of the femoral tunnel. The trailing ends of the graft 82,

84,86, 88 may be fixed to the tibia in accordance with the surgeons preference and in accordance with techniques known in the art.

[0064] A suitable type of graft for use with the present invention is a double-looped semitendinosus and gracilis (DLSTG) hamstring graft which may be prepared in accordance with techniques known in the art.

[0065] A suitable material for the screw would be a combination of ceramic and polymer materials. A suitable ceramic component could be tri-calcium phosphate or ceramic hydroxyapetite. However, any suitable bio ceramic may be used. The polymer component may incorporate poly lactic acid to provide good biocompatibility.

[0066] The reader's attention is directed to all papers and documents which are filed concurrently with or previous to this specification in connection with this application and which are open to public inspection with this specification, and the contents of all such papers and documents are incorporated herein by reference.

[0067] All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive.

[0068] Each feature disclosed in this specification (including any accompanying claims, abstract and drawings), may be replaced by alternative features serving the same, equivalent or similar purpose, unless expressly stated otherwise. Thus, unless expressly stated otherwise, each feature disclosed is one example only of a generic series of equivalent or similar features.

[0069] The invention is not restricted to the details of the foregoing embodiment(s). The invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.